

APPLICANT: Daniel Chain  
SERIAL NO.: 09/975,932  
FILED: October 15, 2001  
Page 5 of 5

Examples section. Applicant maintains that the amendments contain no new matter. Applicant respectfully requests entry of the Amendments.

REJECTION UNDER 35 USC 112 FIRST PARAGRAPH

In the Office Action, the Examiner asserted that claims 1-27 are rejected under 35 USC 112 first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the Examiner asserted that Claims 1-27 allegedly lack enablement because the art teaches that the administration of antibodies to human AD patients resulted in significant complications such that clinical trials had to be suspended. The Examiner asserted that after four months of treatment, where a vaccine comprising A $\beta$  was administered to mildly to moderately afflicted AD patients in a phase II trial, the trial was suspended because some of the patients showed signs of central nervous system inflammation, and two patients had strokes. Further, the Examiner asserted that those individuals affected negatively by the peptide vaccine, exhibited a worsening of the Alzheimer's symptoms such as confusion and inability to perform basic living tasks.

In response, Applicants traverse the Examiner's assertion that the claims are not enable to one skilled in the art to make or use the invention. Applicant disagrees with the Examiner's assertion that the art cited by the Examiner teaches anything relevant to the subject matter defined by the claims. The Elan/Wyeth Phase II trial of AN-1792 is not relevant to the methods of delaying or inhibiting or suppressing the accumulation of an amyloid  $\beta$  peptide or fragment thereof in a brain of a mammal by using the recombinant DNA molecule comprising a gene encoding the recombinant antibodies of the invention.

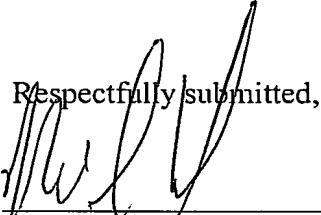
The Elan/Wyeth Phase II trial of AN-1792 was a vaccine trial involved injection of the toxic peptide A $\beta$ 1-42. The subject matter defined by claims 1-27 do not involve injection of a toxic peptide. Rather, the method of the invention comprises the steps of contacting a composition comprising a recombinant DNA molecule, containing a gene encoding a recombinant antibody molecule end specific for the N-terminus or the C-terminus of an amyloid beta peptide, operably linked to a promoter which is expressed in the central nervous system, to a mammal, thereby delaying or inhibiting or suppressing the accumulation of an amyloid  $\beta$  peptide or fragment thereof in a brain of a mammal.

APPLICANT: Daniel Main  
SERIAL NO.: 09/975,932  
FILED: October 15, 2001  
Page 6 of 5

Based on the foregoing, Applicants request allowance of the claims. Should the Examiner have any question or comment as to the form, content or entry of this Amendment, the Examiner is requested to contact the undersigned at the telephone number below.

No fee is deemed necessary for filing this Amendment. However, if any fee is required, the undersigned Attorney hereby authorizes the United States Patent and Trademark Office to charge 05-0649.

Respectfully submitted,

  
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